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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,601	07/05/2001	Gunter A. Hofmann	GENE1200-10	6087

35938 7590 07/29/2003

BIOTECHNOLOGY LAW GROUP  
658 MARSOLAN AVENUE  
SOLANA BEACH, CA 92075

EXAMINER

KENNEDY, SHARON E

ART UNIT PAPER NUMBER

3762

DATE MAILED: 07/29/2003

15.

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/900,601**Applicant(s)  
**Hofmann et al.**Examiner  
**Sharon Kennedy**Art Unit  
**3762**

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 3, 5-27, and 58 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 5-27, and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

#### ***Response to Amendment***

2. Applicant should note that the amendments to the specification and the title have been manually entered by the examiner as agreed during the telephone interview to expedite prosecution.

#### ***Double Patenting***

3. Claims 2, 3, 5-27 and 58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of U.S. Patent No. 6,233,482. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of this application encompass the claims of the '482 patent. Applicant's comments are noted, but the claims of this application are broader than the patented parent, so this rejection is proper. Applicant also argues that the patents will expire simultaneously given the effective filing dates, however, the PTO is still requiring these rejections to ensure that similar claims are commonly owned.

#### ***Claim Rejections - 35 USC § 103***

4. Claims 58, 2, 3, 5-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mir et al., U.S. 5,674,267. Mir discloses the method of increasing the permeability of a cells membrane by applying electric pulses to the cell in order to facilitate the transport of an active agent. Mir does not disclose pairs of electrodes, rather Mir discloses a single central reference

electrode surrounded by the opposing electrodes. See, for example, figures 5, 6, 7 and the description thereof. It would be obvious to one of ordinary skill in the art to assemble electrode pairs as opposed to that shown by Mir since it is reasonable to assume that the devices will behave and operate almost identically. Regarding claim 6, Mir does not specifically state that the device can be used in vitro or ex vivo, Mir only states that the needles are to be inserted into cancer tissue, assumably in the body. However, it would be obvious to one of ordinary skill in the art to treat the tissue in vitro or ex vivo, for the purpose of experimentation to ensure that the in vivo process is viable. Regarding claims 18-21, Mir generically states that the device and method are useful for treating tumors and cancer. It would be obvious to one of ordinary skill in the art to apply the Mir method and device on any specific tumor in the lack of a showing of criticality and in order to widen the range of application for the Mir device. Regarding the needle array of claim 22, it would be obvious to select any number of needles dependent on the tumor size variable. Regarding the route of administration of the drug, it would be obvious to one of ordinary skill in the art to deliver the drug by any means, dependent of the comfort of the patient versus the in vivo stability of the drug being administered. Regarding the specific genes and proteins, these drugs are known for the treatment of various cancers, etc. with electroporation, and applicant has not shown any particular unexpected advantage with any individual element over the prior art, accordingly, it is seen as obvious to deliver any medicament that is needed by the patient in the absence of a showing of unexpected success.

*Response to Arguments*

5. Applicant's arguments filed April 25, 2003 have been fully considered but they are not persuasive. Applicant does not address the almost identical construction of Mir as compared to the claimed invention and has not elaborated on why applicant's apparent minor modification might be patentable.

*Conclusion*

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Kennedy whose telephone number is (703) 305-0154.

July 27, 2003

  
Sharon Kennedy  
Primary Examiner